

Application No. 10/677,694  
Docket No. IB-8 (A4-1770)  
Amendment dated February 2, 2006  
Reply to Office Action of November 2, 2005

**Amendments to the Drawings:**

The attached three (3) sheets of drawings include changes to Figures 2 and 3 and present a new Figure 6. These sheets, which include Figures 1-6, replace the original drawing sheets that included Figures 1-5. In Figures 2 and 3, the lead lines have been rerouted to more precisely point to the features being identified. In new Figure 6, a block diagram is shown of the closed-loop pacing/ICD tuning system described in the first full paragraph on page 11 of the specification.

Attachment(s): Replacement Sheet(s) (3)

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### **REMARKS**

In the Office Action, the Examiner reviewed claims 1-72 of the above-identified US Patent Application, with the result that the specification and drawings were objected to, claims 1-4, 8-10, 13, 23, 24, 29, 30, 41, 42, 44, 45, 47, 49, 52, 53, 55, 59, 63, 64, 68, 69, 70, and 72 were objected to for informalities, claims 25, 26, 42, 43, 45, 47, 50, 51, and 53 were rejected under 35 USC §101, claim 53 was rejected under 35 USC §112, second paragraph, and all but claims 31, 32, 60-63, and 65-68 were rejected under 35 USC §102. Claims 31, 32, 60-63, and 65-68 (which depend from either claim 1 or 2) were deemed to recite allowable subject matter. In response, Applicants have amended the specification, drawings, and claims as set forth above. More particularly:

The specification has been reviewed and amended to provide consistency of terminology, address typographical and grammatical matters, and otherwise address potential issues under 35 USC §112, second paragraph.

The specification has also been amended at pages 5 and 11 to refer to new Figure 6, insert reference numbers to identify the components described at page 11 and shown in Figure 6, and clarify that the "reader unit" and "external reader" discussed at page 11 is the same "reader unit" and "external

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reader" 104/202 discussed elsewhere in the specification, such as the last full paragraph on page 3 ("reader unit"), the paragraph bridging pages 6 and 7 ("external reader 104"), and the first full paragraph on page 7 ("external reader 202"). These amendments to the specification are also believed to be consistent with and find antecedent basis in claims 60-68 as filed.

A substitute Abstract has been presented that more closely describes the invention of the pending claims.

Independent claims 1 and 2 have been amended to recite that the at least one sensing device is implanted in a cavity of the patient's cardiovascular system. Support for this limitation can be found in Applicants' specification in last full paragraph of page 5 and the paragraph bridging pages 5 and 6.

Dependent claim 45 has been canceled (without prejudice to Applicants) and its limitations incorporated into its parent claim 1.

Dependent claim 64 has been canceled (without prejudice to Applicants) and its limitations incorporated into its parent claim 2 and the limitations of claims 65-67 have been incorporated into claim 2 through a Markush group, pursuant to the Examiner's conclusion that each of claims 65-67 (which depend from claim 64) recites allowable subject matter. As such, independent claim 2 and claims depending therefrom are believed to be allowable over the prior art of record.

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Dependent claim 31 has been rewritten in independent form to have a preamble encompassing both independent claims 1 and 2 and to include all of the limitations of its base claim 1, pursuant to the Examiner's conclusion that claim 31 recites allowable subject matter. As such, claim 31 is believed to be allowable over the prior art of record.

All of the claims have been reviewed and amended as necessary to correct matters of a grammatical and typographical nature. In particular, claims 27-30, 41, 57, 58, 70, and 72 have been amended to eliminate the potentially indefinite phrase "but is not limited to," claims 15 and 16 have been rephrased consistent with the second full paragraph on page 11, claims 17-22 have been amended to clarify the resonant, passive, and active "schemes" as relating to coupling of the sensing device to the readout device, as described in the last paragraph on page 6, and claims 62, 63, 67, and 68 have been amended to clarify that the "external reader" is the "readout device" recited in their parent claims 1 and 2.

Applicants believe that the above amendments do not present new matter. Favorable reconsideration and allowance of remaining claims 1-44, 46-63, and 65-72 are respectfully requested in view of the above amendments and the following remarks.

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### **Objection to the Drawings**

The Examiner objected to the drawings under 37 CFR §1.83(a) for failing to show every feature of the invention specified in the claims. In particular, the Examiner explained that the expandable tine in claims 47 and 55 and the embodiment of claims 61-63 and 65-68 must be shown or the features cancelled from the claims.

In response, Applicants have canceled reference to an expandable tine in claims 47 and 55, and have presented new Figure 6 as described above.

Applicants believe that new Figure 6 does not present new matter, in that Figure 6 is merely a block diagram of components described in the application as filed and therefore does not go beyond the scope of the application as filed. Therefore, Applicants respectfully request withdrawal of the Examiner's objection under 37 CFR §1.83(a).

### **Objection to the Specification**

The Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter, citing 37 CFR §1.75(d)(1) and MPEP §608.01(o). Specifically, the Examiner maintained that

The specification lacks sufficient antecedent basis for the embodiment of claims 61-63 and 65-68 having both a readout device comprising a coil allowing electromagnetic

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telecommunication and wireless powering and a separate external reader for transmitting power of receiving data.

Claims 61-63 recite the same limitations as claims 66-68. Applicants believe claim 60 is also relevant to this objection, since claim 60 recites the same limitation as claim 65. As-filed claims 59-63 are reproduced below for the convenience of the Examiner.

59. The system of claim 1 wherein said system is part of a closed-loop pacing/ICD (implantable cardioverter defibrillator) tuning mechanism wherein said sensor data is sent to a patient pacemaker for tailoring of pacing/ICD function.

60. The system of claim 59 wherein said sensor is directly interrogated by the pacing/ICD unit.

61. The system of claim 59 wherein said sensor is interrogated by the pacing/ICD unit wherein an additional external unit is used for the sole purpose of transmitting power to said sensor.

62. The system of claim 59 wherein said sensor transmits data to an external reader, after which said reader retransmits data to the pacing/ICD unit.

63. The system of claim 62 wherein said external reader said pacing/ICD unit perform at least one function of interrogation or powering of the sensor.

As now amended, claims 62 and 63 clarify that the recited "external reader" is the same "readout device" recited in parent claims 1 and 2.

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The paragraph relating to the limitations of claims 60-68 is on page 11 of the specification, and is reproduced below as now amended for the convenience of the Examiner.

The system may be implemented as a closed-loop pacing/ICD (Implantable Cardioverter Defibrillator) tuning system as represented in Figure 6, in which sensor data is fed to a patient pacemaker of a pacing/ICD unit 106 for tailoring of pacing/ICD function. The implanted sensor device 101/201 may be directly interrogated by the pacing/ICD unit 106 (i.e. without requiring the intermediate external reader 104/202). It may also be interrogated by the pacing/ICD unit 106, but with an additional, external power unit 107 solely for transmitting power to the sensor device 101/201. Alternatively, the sensor data may first be transmitted to an external reader 104/202 and then re-transmitted to the pacing/ICD unit 106. Finally, the system may be configured such that both an external reader 104/202 and the pacing/ICD unit 106 may interrogate and/or power the sensor device 101/201. (Emphasis added.)

In view of the above, Applicants believe that the specification has been amended for greater consistency (and clarity) with respect to as-filed claims 60-68, in that the external reader 104/202 is now expressly identified with respect to this embodiment (though interrogation can be performed by the pacing/ICD unit 106 and therefore "without requiring" the reader 104/202).

In view of the above, Applicants respectfully request withdrawal of this objection to the specification.

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### **Claim Objections**

The Examiner objected to the claims for various informalities resulting from the application being filed *pro se*. As indicated above, Applicants have reviewed and amended the claims in a manner that Applicants believe complies with the Examiner's helpful suggestions, and therefore respectfully request withdrawal of the objection to the claims.

### **Claim Rejections under 35 USC §101**

The Examiner rejected claims 25, 26, 42, 43, 47, 50, 51, and 53 under 35 USC §101 as being directed to non-statutory subject matter, specifically, for positively claiming "the body and its parts." However, Applicants respectfully believe that these claims do not positively claim any portion of the human body as elements of Applicants' claimed system, but merely describe the positively claimed elements of the claimed system (i.e., the "sensing device," its "anchoring mechanism," and the "readout device") in their working environment, consistent with the preamble and serving to distinguish the claimed system from, for example, a system comprising a sensing device and readout device used to monitor a machine.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §101.



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### **Claim Rejections under 35 USC §112**

The Examiner rejected claim 53 under 35 USC §112 as being incomplete. Applicants have amended the claim 53 (which depends from claim 2) consistent with claim 45 (which depends from claim 1). As such, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC §112.

### **Prior Art Rejections under 35 USC §102**

Independent claim 2 and most of its dependent claims were rejected under 35 USC §102, while its dependent claims 65-68 were deemed to recite allowable subject matter. As noted above, Applicants have amended claim 2 to incorporate the limitations of claims 65-67 through a Markush group, such that claim 2 requires all limitations of any one of claims 65-67. Applicants therefore respectfully request withdrawal of the rejections under 35 USC §102 of claim 2 and its remaining dependent claims 4, 7, 8, 10, 13, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 35, 36, 39, 40, 49-56, 58, 65-68, 71, and 72.

Applicants respectfully request reconsideration of the remaining rejections of independent claim 1 and its remaining dependent claims in view of the amendments presented above as well as the following comments.

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Applicants' amended independent claim 1 requires the limitation from its original dependent claim 45, which was subjected to rejections under 35 USC §102 based on U.S. Patent No. 6,636,769 to Govari et al. (Govari) and U.S. Patent No. 6,409,674 to Brockway et al. (Brockway). In particular, amended claim 1 requires

at least one sensing device implanted in a cavity of the patient's cardiovascular system, said sensing device comprising an anchoring mechanism, at least one inductor coil and at least one sensor, with optional electronic components, said at least one sensing device being implanted so that a portion of said anchoring mechanism passes through a septum of the heart and, to minimize the risk of thrombogenicity, a larger portion of said implantable sensing device is located in the right side of the heart and a smaller portion of said implantable sensing device is located in the left side of the heart and includes the at least one sensor; . . . .

Though Figure 11 of Govari was cited for disclosing the limitation of a larger portion of an implantable device 50 located on the right side of the heart and a smaller portion located in the left side of the heart, Govari discloses just the opposite: the larger portion 68 of Govari's device 50 is located on the left side (left atrium 410) of the heart 400 and the smaller portion 64 is located in the right side (right atrium 415) of the heart 400. See and compare Figures 10 and 11 of Govari. Therefore, Applicants believe that Govari does not disclose, teach, or suggest Applicants' invention as it is recited in independent claim 1.

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Though Figures 3A-D and column 8, lines 26-52, of Brockway were cited for disclosing the limitation of a larger portion of an implantable device 105 located on the right side of the heart and a smaller portion located in the left side of the heart, Applicants can find no teaching in Brockway to this effect. Instead, Brockway appears to be limited to inserting a screw 312A, harpoon 312B, mesh 312C, or expandable stabilizer 312D into, but not through, a wall of the heart. Therefore, Applicants believe that Brockway also does not disclose, teach, or suggest Applicants' invention as it is recited in independent claim 1.

For the above reasons, Applicants respectfully request withdrawal of the rejections to claim 1 and its dependent claims under 35 USC §102.


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**Closing**

In view of the above, Applicants believe that all issues outstanding from the Office Action have been addressed, and that the claims define patentable novelty over all the references, alone or in combination, of record. It is therefore respectfully requested that this patent application be given favorable reconsideration.

Should the Examiner have any questions with respect to any matter now of record, Applicants' representative may be reached at (219) 462-4999.

Respectfully submitted,

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Attachments: Replacement Drawing Sheet(s); Replacement Abstract